UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,855	06/22/2001	Dirk M. Anderson	2883-US	8635

22932 7590 04/20/2005

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,855	ANDERSON, DIRK M.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21,23-28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21, 23-28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants' Amendment and Response to office action dated October 4, 2004 filed on January 28, 2005 is acknowledged. Claims 1-13 have been canceled. Claims 14, 17, 24, 30-33 have been amended. Claims 22 and 29 are withdrawn from the prosecution. Therefore, claims 14-21, 23-28 and 30-33 are currently pending and are under examination.

Response to Arguments and Remarks

Rejection under *35 USC § 102(e)*

Rejection of claims 30, 31, 32 and 33 as being anticipated by Komatsoulis et al. is withdrawn in view of remarks at page 4 of the 'Amendment and Response.'

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 stand/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting binding between a ss3939 polypeptide and a binding partner of said ss3939 polypeptide, does not reasonably provide enablement for all the soluble proteins, and fragments or mutants generated from any position located on the sequence of the ss3939 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification has disclosed a method for inhibiting binding between ss3939 polypeptide and a binding partner of said ss3939 and variants thereof, wherein the binding partner is expressed by human umbilical vein endothelial cells. There is no

guidance as to how the functional fragments and mutants of the claimed ss3939 protein can be generated. The specification has provided no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein, which are tolerant to change (e.g. by amino acid deletions, insertions or substitutions), and the nature and extent of changes that can be made in these positions. Although the specification outlines generic procedures for producing and screening for protein variants, this is not adequate guidance as to the nature of specific active derivatives that may be constructed. Given the lack of teachings or guidance in applicants' disclosure regarding the variants of soluble protein other than the one specifically referenced Fc fusion protein, such as ss3939/Fc described in Examples 2 and 5, it would require undue experimentation by one skill in the art to make mutants/fragments of ss3939 polypeptide or other undefined molecules having an activity substantially equivalent to that of ss3939 polypeptide, commensurate in scope with the claims.

In response Applicants traverse these grounds for rejection. The reason for traversal is the office action has provided no evidence that the alleged experimentation would be beyond that which is considered routine to one of skill in the art. It was stated in the previous office action and also in this office action (supra) that "it would require undue experimentation by one skill in the art to make mutants/fragments of ss3939 polypeptide or other undefined molecules having an activity equivalent to that of a full length ss3939 polypeptide." It was also stated that the specification outlines generic procedures for producing and screening for protein variants, this is not adequate guidance as to the nature of specific active derivatives that may be constructed. Moreover, the experimentations considered routine are also considered undue to one of skill in the art.

Further, Applicants have stated at pages 2-3 that the specification (pages 10-11) provides structural information useful for identifying regions to be considered for producing soluble polypeptides, such as the extracellular and intracellular domain. The specification and the Exhibits 1 and 2 have been reviewed. Applicants arguments have been considered but not found persuasive because the identification of soluble polypeptide producing regions such as extracellular and intracellular domains have 206 amino acids and 126 amino acids respectively (specification page 10). The specification

has provided no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the specific positions in the extracellular and intracellular domains of the protein, which are tolerant to change (e.g. by amino acid deletions, insertions or substitutions), and the nature and extent of changes that can be made in these positions.

Applicants have provided Exhibit 1 and 2 as examples of the knowledge in the prior art and the level of skill of those in the art regarding C-type lectins. Exhibits 1 and 2 have been reviewed but the molecular model of the carbohydrate binding domain in rat mannose-binding protein (MBP) (Exhibit 1) and its sequence comparison with C-type lectin domains from human E-selectin, rat macrophage lectin (ML) and with SEQ ID NO: 2 of instant application (Exhibit 2) are not sufficient to enable those of skill in the art to practice the claimed invention. Only by having a carbohydrate binding domain, the soluble ss3939 cannot have the similar function as the C-type lectin proteins. Thus, without knowing the function of a soluble polypeptide ss3939 variants it would require undue experimentation to make variants that are at least 90% or 95% identical to amino acids 22-through 227 of SEQ ID NO: 2 and that bind to human umbilical vein endothelial cells. Undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14, 24, 30 and the dependent claims thereto stand/are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Bringing the polypeptide to the contact of a binding partner, for example contacting of an endogenous ss3939 to the cells expressing surface binding partners; inhibition of binding step; and the ultimate biological effects that result from inhibiting ss3939 polypeptide binding with a binding partner. Claims 15-21, 23, 25-28 and 31-33

are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claims from which they depend upon.

Applicants' arguments are considered but not found persuasive because the cited reference to MPEP § 2172.01 does provide for rejections under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, please see Form Paragraph 7. 34.12.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954.

The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
April 16, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER